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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/726,433

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Douglas J. Duchon

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08/25/2006

INSKEEP INTELLECTUAL PROPERTY GROUP, INC
2281 W. 190TH STREET
SUITE 200
TORRANCE, CA 90504

EXAMINER

PETRIK, KARI KRISTEN

ART UNIT

PAPER NUMBER

3743

DATE MAILED: 08/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/726,433

Applicant(s)

DUCHON ET AL.

Examiner

Kari Petrik

Art Unit

3743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 6-53, 55, 57, 58, 60-65 and 67 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 6-13, 19-21, 23-30, 32-38, 41-46, 48 and 52 is/are rejected.
- 7) ☐ Claim(s) 4, 14-18, 22, 31, 39, 47, 49-51, 55, 57, 58, 60, 63-65, 67 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. The amendment filed on 3/1/2006 has been received and made of record. As requested, claims 1, 10, 19, 36, 44, 51-53, 57, 60-61, and 67 have been amended, and claims 5, 40, 54, 56, 59, and 66 have been cancelled.

Claim Objections

1. Claims 4, 18, 22, 31, 39, 51, 53, and 61 are objected to because of the following informalities: it appears that "menorragia" should be spelled --menorrhagia--. Appropriate correction is required.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-3, 6-13, 19-21, 23-30, 32-38, 41-46, 48, and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vancaillie (US Patent 5,095,917).

4. Regarding claim 1, Vancaillie discloses a method of changing a gynecological condition of a female comprising introducing an implant (32) into the uterus with a delivery tool (30),

Art Unit: 3743

contacting the implant with the uterine tissue so as to induce a tissue response, detaching the implant from the delivery tool, and maintaining contact between the implant and uterine tissue until at least a portion of the walls of the uterus adhere together (see Figure 6) and cause a changed gynecological condition in the female.

Vancaillie fails to teach evaluating the condition of a uterus of said female and further fails to teach that the implant is a presterilized implant. The examiner, however, contends that both limitations are either inherent and/or would have been obvious to one having ordinary skill in the art the time of invention. More specifically, it would have been obvious to one having ordinary skill in the art to evaluate the condition of the uterus of a patient prior to the procedure. Further, it would have been obvious *prima facie* to one having ordinary skill in the art to insert a presterilized implant in order to prevent the spread of bacteria into the uterus.

5. Regarding claim 2, contact between the implant and uterine tissue is maintained at least until adhesions are formed (see Figure 6 where the walls are adhered together and column 3, lines 23-45).

6. Regarding claim 3, contact is maintained until the uterotubal junction is blocked, hence contraception in the uterus is achieved.

7. Regarding claims 6 and 7, Vancaillie discloses that the implant can include an adhesion inducing substance (column 3, lines 60-63) applied before introducing the implant into the uterus.

8. Regarding claim 8, Vancaillie fails to teach that the device is constructed from polyester. However, it has been held that the selection of a material based upon its suitability for the intended use is a design consideration within the level of ordinary skill in the art. *In re Leshin*,

Art Unit: 3743

227 F.2d 197, 125 USPQ 416 (CCPA 1960). Thus, absent a critical teaching and/or a showing of unexpected results derived from the use of polyester as a material of construction for the implant, the examiner contends that it would have been an obvious design choice to one having ordinary skill in the art at the time the invention was made to use polyester or any other material that is suitable.

9. Regarding claim 9, Vancaillie discloses the use of a delivery tool, but fails to teach the delivery tool is a catheter. However, the examiner contends that it would have been *prima facie* obvious to one having ordinary skill in the art to insert the implant into uterus with a catheter since they are well known delivery tools for implants for use throughout the entire human body.

10. Regarding claim 10, note the rejection of claim 1 above.

11. Regarding claim 11, Vancaillie discloses the implant (plug) may be of any suture material that acts as a matrix for ingrowth of fibroblasts, but does not disclose the implant is of a mesh material. However, it has been held that the selection of a material based upon its suitability for the intended use is a design consideration within the level of ordinary skill in the art. *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960). Thus, absent a critical teaching and/or a showing of unexpected results derived from the use of mesh as a material of construction for the implant, the examiner contends that it would have been an obvious design choice to one having ordinary skill in the art at the time the invention was made to use mesh or any other material that is suitable.

12. Regarding claim 12, note the rejection of claim 8 above.

13. Regarding claim 13, note the rejection of claim 6 above.

14. Regarding claim 19, note the rejection of claim 3 above.

Art Unit: 3743

15. Regarding claim 20, note the rejection of claims 1 and 2.
16. Regarding claim 21, note the rejection of claim 3.
17. Regarding claim 23, the formation of the adhesions includes causing walls of at least a portion of the uterus to adhere together (Figure 6).
18. Regarding claim 24, note the rejection of claim 6.
19. Regarding claim 25, note the rejection of claim 7.
20. Regarding claim 26, note the rejection of claim 8.
21. Regarding claim 27, note the rejection of claim 9.
22. Regarding claim 28, note the rejection of claim 1.
23. Regarding claim 29, note the rejection of claim 2.
24. Regarding claim 30, note the rejection of claim 3.
25. Regarding claim 32, note the rejection of claim 6.
26. Regarding claim 33, note the rejection of claim 7.
27. Regarding claim 34, note the rejection of claim 8.
28. Regarding claim 35, note the rejection of claim 9.
29. Regarding claim 36, note the rejection of claims 1 and 8.
30. Regarding claim 37, note the rejection of claim 2.
31. Regarding claim 38, note the rejection of claim 3.
32. Regarding claim 41, note the rejection of claim 6.
33. Regarding claim 42, note the rejection of claim 7.
34. Regarding claim 43, note the rejection of claim 9.
35. Regarding claim 44, note the rejection of claims 10 and 11.

Art Unit: 3743

36. Regarding claim 45, note the rejection of claims 10, 11, and 12.

37. Regarding claim 46, note the rejection of claim 6.

38. Regarding claim 48, note the rejection of claims 10, 11, and 12.

39. Regarding claim 52, note the rejection of claim 19.

40. Claims 53, 61, and 62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Feldberg et al (US Patent 6,026,331).

41. Feldberg et al disclose an implant (7) for changing the gynecological state of a female comprising a presterilized substance (column 4, lines 12-14) comprised of a frame (5) at least partially covered by a mesh material (8, column 4, lines 8-11). The substance is configured for causing a tissue response and is sized and shaped for sufficiently contacting tissue such that menorrhagia is eliminated (column 1, lines 5-10).

Feldberg et al fail to teach that the mesh material is constructed from polyester. However, it has been held that the selection of a material based upon its suitability for the intended use is a design consideration within the level of ordinary skill in the art. *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960). Thus, absent a critical teaching and/or a showing of unexpected results derived from the use of polyester as a material of construction for the implant, the examiner contends that it would have been an obvious design choice to one having ordinary skill in the art at the time the invention was made to use polyester or any other material that is suitable.

Art Unit: 3743

Allowable Subject Matter

42. Claims 4, 14-18, 22, 31, 39, 47, 49-51, 55, 57, 58, 60, 63-65, and 67 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kari Petrik whose telephone number is 571-272-8057. The examiner can normally be reached on M-Th and every other Friday, 7-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on 571-272-4791. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Kari Petrik
Examiner
Art Unit 3743

KKP


Henry Bennett
Supervisory Patent Examiner
Group 3700